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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,856	02/26/2007	Victor Camfield Windeyer	Q94172	4174

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
SASAKI, SHOGO	
ART UNIT	PAPER NUMBER
1773	

NOTIFICATION DATE	DELIVERY MODE
06/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/573,856	WINDEYER ET AL.	
	Examiner	Art Unit	
	SHOGO SASAKI	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 62-78* is/are pending in the application.

4a) Of the above claim(s) *1-16,18,19,62-75,77 and 78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/29/2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 17 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Windeyer (WO 03029845). Also see U.S. 5282149 for the evidentially teaching (See below).

Regarding claims 17 and 76, Windeyer discloses a tissue processor having two retorts, a controller comprising programmable protocols (page 6), and a set of reagent containers fluidically connected to the retorts by reagent conduits and a valving arrangement, wherein the valving arrangement directs reagent from the reagent containers into either of the retorts, as directed by the controller (pages 3 and 5). The controller controls the tissue processing steps such as fixation, dehydration, clearing and infiltration (page 4).

Windeyer discloses that, in the past, a single protocol may be run, and the protocol must attempt to cater to the range of tissue samples that may be included in a single run (pages 2-3). This can result in either over processing or under processing of some samples (id.). Given the sealed nature of the retort, tissue samples may not easily be removed or added during a processing run (id.). Another issue may be that some samples require urgent processing, while other samples are not urgent (id.). In the known tissue sample preparation apparatus it has not been possible to stop a current sample run to process a sample required urgently, or to employ a protocol that allows an urgently required sample to be processed with other samples that require longer processing times (id.). Thus, either the urgently required sample is run in isolation, or it is put with other samples, increasing the processing time (id.).

Windeyer states that his invention overcomes these issues. Windeyer may not use the term "priority" or the phrase "conflict between protocols." However the examiner asserts that these issue that are to be overcome is inherently disclosed by Windeyer and is obvious.

It would have been obvious to one having ordinary skill in the art at the time of the invention to avoid conflict between process protocols within a multiple retort processing system by giving process precedence preference(s), i.e., priorities, to one process over the other(s); for example (also see page 3 of Windeyer), for the purpose of imposing faster processing time (in favor of one patient to another); or earlier starting time for certain tissue samples (due to longer fixation/staining time needed for the certain samples). That is the basis for scheduling (Also see U.S. 5282149: Grandone. Grandone discloses an adaptive scheduling system and method for a biological analyzer processing different samples based on priority given to the samples. See for e.g., C11-12). It is noted that the claims say nothing more than determining and/or assigning priorities; and modifying one process to accommodate the priority give to another process. It is obvious that one protocol will have to be or should be given a priority (higher or lower) over the other process/protocol. The examiner asserts that skilled artisan would have been motivated to modify a protocol (such as the programmable protocol of Windeyer) as a whole or in part (step(s) of the protocol) to account for the imposed priority.

Response to Arguments

5. Applicant's arguments filed 6/9/2011 have been fully considered but they are not persuasive.

In response to page 2, lines 8-14 of the remark, it is noted that Windeyer reference does not appear to include a specific embodiment, in which additional retorts are introduced to the operation.

However, Windeyer discloses a tissue processor having two retorts, a controller comprising programmable protocols, and a set of reagent containers fluidically connected to the retorts by reagent conduits and a valving arrangement, wherein the valving arrangement directs reagent from the reagent containers into either of the retorts, as directed by the controller.

Windeyer discloses that, in the past, a single protocol may be run, and the protocol must attempt to cater to the range of tissue samples that may be included in a single run. This can result in either over processing or under processing of some samples. Another issue raised by Windeyer is that some samples require urgent processing, while other samples are not urgent. In the known tissue sample preparation apparatus it has not been possible to stop a current sample run to process a sample required urgently, or to employ a protocol that allows an urgently required sample to be processed with other samples that require longer processing times. Thus, either the urgently required sample is run in isolation, or it is put with other samples, increasing the processing time.

Windeyer may not use the term "priority" or the phrase "conflict between protocols." However the examiner asserts that these issue that are to be overcome is inherently disclosed by Windeyer and is obvious.

The examiner respectfully asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention to avoid conflict between process protocols within a multiple retort processing system by giving process precedence preference(s), i.e., priorities, to one process over the other(s); for example (also see page 3 of Windeyer), for the purpose of imposing faster processing time (in favor of one patient to another); or earlier starting time for certain tissue samples (due to longer fixation/staining time needed for the certain samples). That is the basis for scheduling (Also see U.S. 5282149: Grandone. Grandone discloses an adaptive scheduling system and method for a biological analyzer processing different samples based on priority given to the samples. See for e.g., C11-12).

It is noted that the claims say nothing more than determining and/or assigning priorities; and modifying one process to accommodate the priority give to another process. It is obvious that one protocol will have to be or should be given a priority (higher or lower) over the other process/protocol. The examiner asserts that skilled artisan would have been motivated to modify a protocol (such as the programmable protocol of Windeyer) as a whole or in part (step(s) of the protocol) to account for the imposed priority.

In response to page 2, lines 15-25, the examiner disagrees with applicant's contention. Grandone reference is directed towards a method and system for operation

of biological sample analyzer, wherein instrument systems used to perform an assay of each of the biological samples loaded into the analyzer are operated in accordance with a schedule developed by a scheduler routine. The examiner asserts that the scheduling of processes by taking priority given to various samples into account, taught by Grandone is relevant to the instant claims and is pertinent as an evidentially reference for the obviousness rejection presented above.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. From the previous action: The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references: Trumbull (US 20010029320); Farb (US 6048722); DeMoranville (US 5437838); and Ashihara (US

5158895) disclose methods of scheduling sample processing within bio/chemical sample processing apparatuses.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHOGO SASAKI whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS
6/22/10

/BRIAN R GORDON/
Primary Examiner, Art Unit 1773